CALIFORNIA BOARD OF OCCUPATIONAL THERAPY INITIAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Use of Topical Medications

Section Affected: Title 16, Division 39, California Code of Regulations, Section 4152.1

SPECIFIC PURPOSE OF THE REGULATIONS:

Effective January 1, 2005, Senate Bill 1913 (Figueroa, Chapter 695, Statutes of 2004), added Section 2571 to the Occupational Therapy Practice Act (OTPA). Section 2571 authorizes occupational therapists to administer topical medications to a patient via iontophoresis or phonophoresis. The statute requires that the occupational therapist (OT) be authorized by the Board to use physical agent modalities pursuant to OTPA Section 2570.3(d). The existing law further requires that the patient's physician and surgeon, certified nurse-midwife, nurse practitioner, or physician assistant prescribe the topical medication. The Board is required to promulgate regulations specifying those medications applicable to the practice of occupational therapy and protocols for their use. The proposed regulatory action is necessary to implement this legislation.

FACTUAL BASIS/NECESSITY:

Section 4152.1: The application of topical medications (used for pain management) through iontophoresis (electricity) and phonophoresis (ultrasound) is a practice that has been engaged in by occupational therapists (OT) for many years. Iontophoresis and phonophoresis are physical agent modalities as defined by Section 2570.2(m) of the OTPA. The proposed regulations will limit the application of topical medications to administration via iontophoresis and phonophoresis. Any medication applied must be ordered on a specific or standing basis by a practitioner legally authorized to order or prescribe such medication.

The proposed regulations require that written protocols be prepared for the administration of the topical medications. The industry standard is for each facility to establish protocols for equipment use. Typically these protocols are based on instructions which are included by the manufacturer of the iontophoresis and phonophoresis equipment. The regulation requires that the protocols include a description of the medication, its actions, its indications and contraindications, and the proper procedure and technique for the application or administration of medication.

The regulations allow for supervision of the administration of topical medications by an OT in accordance with Title 16, Division 39, California Code of Regulations, Article 9. This will allow occupational therapy assistants, limited permit holders, Level II students, and occupational therapy aides who are under the supervision of OT

approved to use physical agent modalities to apply topical medications via iontophoresis and phonophoresis pursuant to the OTPA.

Existing law requires that the Board meet and confer with the Medical Board of California, the California State Board of Pharmacy, and the Physical Therapy Board of California to specify those topical medications applicable to the practice of occupational therapy and protocols for their use. Representatives from each of these boards attended the Advanced Practice Regulatory Committee meeting held August 25, 2005, and testified in support of OTs applying topical medication. Representatives of each board were provided a copy of draft language prior to approval by the California Board of Occupational Therapy at its November 4, 2005, meeting.

UNDERLYING DATA:

No underlying data was used during the development of these regulations.

BUSINESS IMPACT:

This regulation will not have a significant adverse economic impact on business. The proposed regulation will only affect licensees and certificate holders.

SPECIFIC TECHNOLOGIES OR EQUIPMENT:

The proposed regulation limits the method of application of topical medications to iontophoresis and phonophoresis. The specific purpose of iontophoresis and phonophoresis equipment is to deliver medication through the skin during the course of occupational therapy treatment. The purpose of the proposed regulation is to implement the statute authorizing OTs to use apply topical medications via iontophoresis and phonophoresis.

CONSIDERATION OF ALTERNATIVES:

No reasonable alternative to the regulation would be either more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons than the proposed regulations.